REMARKS

Claims 1-16 were pending in the application. Claims 6-16 have been withdrawn from consideration by the Office (following election) and were canceled by Applicants, for ease of consideration. Claims 1-5 were examined by the Office.

Applicants have added claims 17-24. Thus, claims 1-5 and 17-24 are presently before the Office for examination. New claims 17-20 recite subject matter that belongs to the same group elected by Applicants in the June 2006 restriction requirement. No new matter is added by way of the instant amendments.

Applicants will timely file divisional applications to the non-elected subject matter recited in original claims 6-16.

§112, Second Paragraph

Applicants amended claims 1, 4 and 5. Claim 1 now includes recitations to better reflect the claimed subject matter; claim 4 now recites the human proximal tubule derived cell line is HK-2; and claim 5 now recites the PPAR responsive gene is ADRP.

Applicants respectfully submit that the rejection of claims 1, 2, 4 and 5 under §112, 2nd paragraph should be withdrawn.

§112, First Paragraph (Written Description)

To the extent that Applicants' amendments to not obviate the Office's §112, 1st paragraph positions, Applicants respectfully traverse the Office's written description position regarding claims 1-5. The Office cites and relies upon a number of cases involving written description of composition of matter/product claims (*e.g., Fiddes and Vas-Cath*). Reliance on those cases is misplaced for purposes of the method claims currently under examination. The proper inquiry is whether the application, at the time of filing, would have conveyed to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. That is, were Applicants in possession of a cell based assay (*i.e.*, method) for evaluating cellular responses to PPAR ligands in claim 1 (and claims dependent thereon). The Office has advanced no *prima facie* evidence providing the perspective of one of ordinary skill in the art and his or her perceptions of the description provided in the application, at the time of filing. Thus the written description analysis is flawed.

Additionally, the Office appears to require that Applicants describe each and every PPAR responsive gene in Applicants' application. Applicants provide examples of such genes (e.g., PDK-4 and ADRP) and one of ordinary skill in the art would have been able to turn to existing knowledge in the art for additional PPAR responsive genes for use in Applicants' assay. In fact, the very references cited by the Office provide a number of PPAR responsive genes and

one of ordinary skill in the art would have been aware of that information (*e.g.*, cPLA2 as in Jiang, any of the 69 genes listed in Table 2 of Way et al.; and ALDH2 of Crabb *et al.*).

In view of the above, Applicants respectfully submit that as of the filing date of the instant application (September 2003) one of ordinary skill in the art reading the instant application would have concluded that Applicants were in possession of the assays recited in the claims. Withdrawal of the Office's §112, 1st paragraph position is respectfully requested.

§102 – Way *et al.*, Jiang *et al.*, Crabb *et al.*, and Wu *et al.*

Applicants respectfully traverse the Office's position with respect to Way *et al.*, Jiang *et al.*, Crabb *et al.*, and Wu *et al.* Briefly, none of the cited references teach use of a single dose of PPAR agonist as recited in claims 21-24. Rather the cited references teach multiple dose administration (*e.g.*, facilitating feeding of agonist over a number of days). Additionally, many of the references fail to teach the specific PPAR responsive genes recited in certain claims. (*e.g.*, claims 1 and 17). Withdrawal of the Office's §102 positions is respectfully requested in view of Applicants' comments provided below.

Way

Way *et al.* concerns identification of PPAR responsive genes using a rat *in vivo* system. There is no teaching of an *in* vitro, cell based assay for evaluating cellular responses to PPAR modulators. Additionally, Way fails to teach or describe that the PPAR responsive gene is ADRP or PDK-4. Finally, Way fails to teach administration of a single dose of PPAR modulator. Applicants respectfully submit that, *inter alia,* these distinctions remove Way as an anticipatory reference.

Jiang *et al.*

Jiang *et al.* concerns evaluation of the interplay between PPARs and cytosolic phospholipase A_2. There is no teaching that the PPAR responsive gene is ADRP or PDK-4. Additionally, Jiang fails to teach administration of a single dose of PPAR modulator. Applicants respectfully submit that, *inter alia,* these distinctions remove Jiang as an anticipatory reference.

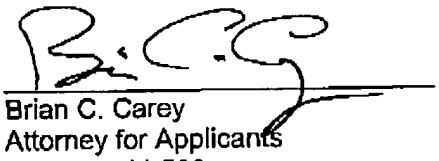
Crabb *et al.* and Wu *et al*

Crabb and Wu similarly fail to teach each element of the instant claims. There is: no teaching of PDK-4 or ADRP as the PPAR responsive gene; no teaching of single-dose administration of PPAR agonist; and no teaching of an *in vitro* cell based assay.

In view of the foregoing, Applicants respectfully request withdrawal of the Office's §102 positions. Should the Office wish to discuss the instant application further, please contact the undersigned.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 19-3880 in the name of Bristol-Myers Squibb Company.

Respectfully submitted,



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